

Serial No.: 10/533,734
Group Art Unit No.: 1648

AMENDMENTS TO THE CLAIMS

Listing of the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) A pharmaceutical composition comprising a [[A]] polynucleotide that comprises a sequence encoding an HIV gp120 envelope protein, which is substantially non-glycosylated when expressed in a mammalian target cell, operably linked to a heterologous promoter, wherein the HIV gp120 envelope protein is adapted to reduce or prevent glycosylation lacking a functional secretion signal and is substantially non-glycosylated when expressed in a mammalian target cell, and at least one pharmaceutically acceptable excipient, diluent, and/or carrier.

2. - 3. (Cancelled)

4. (Currently amended) The polynucleotide according to claim 2 pharmaceutical composition of claim 1, wherein the gp120 encoding sequence is expressed as a fusion protein comprising at least one other HIV protein.

5. (Currently amended) The polynucleotide according to claim 4 pharmaceutical composition of claim 4, wherein the other HIV protein is selected from the group of: Nef, Gag, RT and Tat.

6. (Currently amended) The polynucleotide according to claim 4 pharmaceutical composition of claim 4, wherein the gp120 encoding sequence is linked to a sequence encoding HIV RT and a sequence encoding HIV Gag and a sequence encoding HIV Nef to encode a gp120, RT, Gag and Nef-containing fusion protein.

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7. (Currently amended) The ~~polynucleotide according to claim 6~~pharmaceutical composition of claim 6, wherein the fusion protein is selected from:
a fusion protein comprising in the 5' to 3' direction: gp120-RT-Nef-Gag, and
a fusion protein comprising in the 5' to 3' direction: RT-Nef-Gag-gp120.
8. (Currently amended) The ~~polynucleotide according to claim 4~~pharmaceutical composition of claim 4, wherein the gp120 sequence is linked to a sequence encoding HIV Tat and a sequence encoding HIV Nef to encode a gp120, Nef and Tat-containing fusion protein.
9. (Currently amended) The ~~polynucleotide according to claim 8~~pharmaceutical composition of claim 8, wherein the fusion protein comprises in the 5' to 3' direction: is a gp120-Nef-Tat fusion.
10. (Currently amended) The ~~polynucleotide according to claim 8~~pharmaceutical composition of claim 8, wherein the gp120 encoding sequence is further linked to a sequence encoding HIV Gag to encode a gp120, Nef, Tat and Gag-containing fusion protein.
11. (Currently amended) The ~~polynucleotide according to claim 10~~pharmaceutical composition of claim 10, wherein the fusion protein comprises in the 5' to 3' direction: is a gp120-Gag-Nef-Tat fusion.
12. (Currently amended) The ~~polynucleotide according to claim 5~~pharmaceutical composition of claim 5, wherein the Gag comprises one or both of P17 and P24.
13. (Currently amended) The ~~polynucleotide according to claim 5~~pharmaceutical composition of claim 5, wherein at least one of the sequences encoding gp120, Nef, Gag, RT and Tat is codon optimised to resemble codon usage in a highly expressed human gene.

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14. (Currently amended) A pharmaceutical composition comprising a nucleic acid comprising in the 5' to 3' direction a polynucleotide sequence selected from the group of:

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal – tr Nef,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal – tr Nef – mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal – Nef - mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal – p17/24 Gag – tr Nef,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal – p17/24 Gag – tr Nef - mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - Nef-mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - mNef-mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - L1Nef-mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - L2Nef-mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - LLNef-mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - mLLNef-mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - mL1Nef-mTat,~~

codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal - p17/24 Gag - mL2Nef-mTat,~~

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codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal~~ - mRT- trNef - p17/24 Gag, and
mRT – trNef – p17/24 Gag – codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal~~,
~~Wherein~~wherein the RT and Gag are codon optimized,
and at least one pharmaceutically acceptable excipient, diluent, and/or carrier.

15 (Currently amended) The polynucleotide according to claim 1~~pharmaceutical composition of claim 1~~, wherein the promoter is from an HCMV IE gene.

16. (Currently amended) The polynucleotide according to claim 15~~pharmaceutical composition of claim 15~~, wherein a 5' untranslated region comprising exon 1 of the HCMV IE gene ~~is~~ between the promoter and the coding sequences ~~comprises exon 1~~.

17. (Currently amended) A pharmaceutical composition comprising a set of polynucleotides comprising the ~~[[a]]polynucleotide of according to claim 1~~, and at least one further polynucleotide encoding at least one chosen from the group of: HIV Nef, Gag, RT and Tat.

18. (Currently amended) The pharmaceutical composition of claim 17~~set of polynucleotides according to claim 17~~, wherein the polynucleotides are contained on a single vector under the control of at least one separate promoter.

19. (Currently amended) The pharmaceutical composition of claim 17, wherein the set of polynucleotides comprises a polynucleotide according to claim 17, encoding a gp120 and a polynucleotide encoding a fusion protein comprising in the 5' to 3' direction: [[of]]RT-Nef-Gag.

20. (Currently amended) The pharmaceutical composition of claim 17~~A set of polynucleotides according to claim 17~~, comprising in a 5' to 3' direction a polynucleotide sequence selected from:

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codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal,~~
codon optimized gp120 lacking a secretion signal ~~gp120 codon optimised, minus secretion signal~~ + P17/24 Gag - tr Nef,
codon optimized gp120 lacking a secretion signal ~~gp120 codon optimised, minus secretion signal~~ + P17/24 Gag - Nef - mTat,
mRT - tr Nef - P17/24 Gag + codon optimized gp120 lacking a secretion signal~~gp120 codon optimised, minus secretion signal,~~
codon optimized gp120 lacking a secretion signal ~~gp120 codon optimised, minus secretion signal~~ + mRT - tr Nef - P17/24 Gag,
wherein RT and Gag are codon optimised.

21. (Currently amended) The pharmaceutical composition of claim 1, wherein the polynucleotide sequence encoding the gp120 is in a vector~~A vector comprising a polynucleotide as claimed in claim 1.~~

22. (Currently amended) The pharmaceutical composition of claim 21, vector according to claim 21, wherein the vector is a double stranded DNA plasmid.

23. (Currently amended) The pharmaceutical composition of claim 21, vector according to claim 21, wherein the vector is a replication defective adenovirus vector.

24. (Currently amended) The pharmaceutical composition of claim 23, vector according to claim 23, wherein the vector is derived from the group of: Pan 9, 5, 6 and 7.

25. - 27. (Cancelled)

28. (Currently amended) The [[A]]pharmaceutical composition comprising vector according to of claim 1, further comprising 21, and at least one element chosen from the group of: a pharmaceutically acceptable excipient, a diluent, a carrier, and an adjuvant.

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29. (Currently amended) The pharmaceutical composition of ~~according to~~ claim ~~[[28]]~~1, wherein the carrier is a plurality of particles.

30. (Currently amended) The pharmaceutical composition of ~~according to~~ claim ~~[[28]]~~1, wherein the pharmaceutical composition is suitable for delivery in a prime boost format.

31. (Currently amended) An intradermal delivery device comprising the ~~[[a]]~~ pharmaceutical composition of ~~according to~~ claim ~~[[28]]~~1.

32. (Withdrawn-currently amended) A method of treating a patient suffering from or susceptible to a disease caused by HIV comprising administering a safe and effective amount of ~~[[a]]~~the pharmaceutical composition ~~according to~~ of claim ~~[[28]]~~1.

33. - 35. (Cancelled)

36. (Currently amended) The pharmaceutical composition of ~~according to~~ claim ~~[[28]]~~1, wherein the carrier is gold beads.